ADX-102 was Non-inferior to Corticosteroid in a Randomized, Comparator-Controlled Phase 2 Clinical Trial in Noninfectious Anterior Uveitis

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Disclosures

- Alcon: Research Grants, Speaker, Advisor
- Aldeyra Pharmaceuticals: Advisory Board, Clinical Research
- Allergan: Research Grants, Speaker, Advisory Board, Media Spokesman
- Bausch & Lomb, Ista, Valeant: Research Grants, Speaker, Advisory Boards
- Abbvie: Research, Advisor, Spokesman
- BioTissue: Advisory Board, Clinical Research
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- RPS: Advisory, Research, Investor
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- Shire, SarCode Biosciences: Advisory Board, Shareholder, Research Grant
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- Srathspey Crowne: Investor
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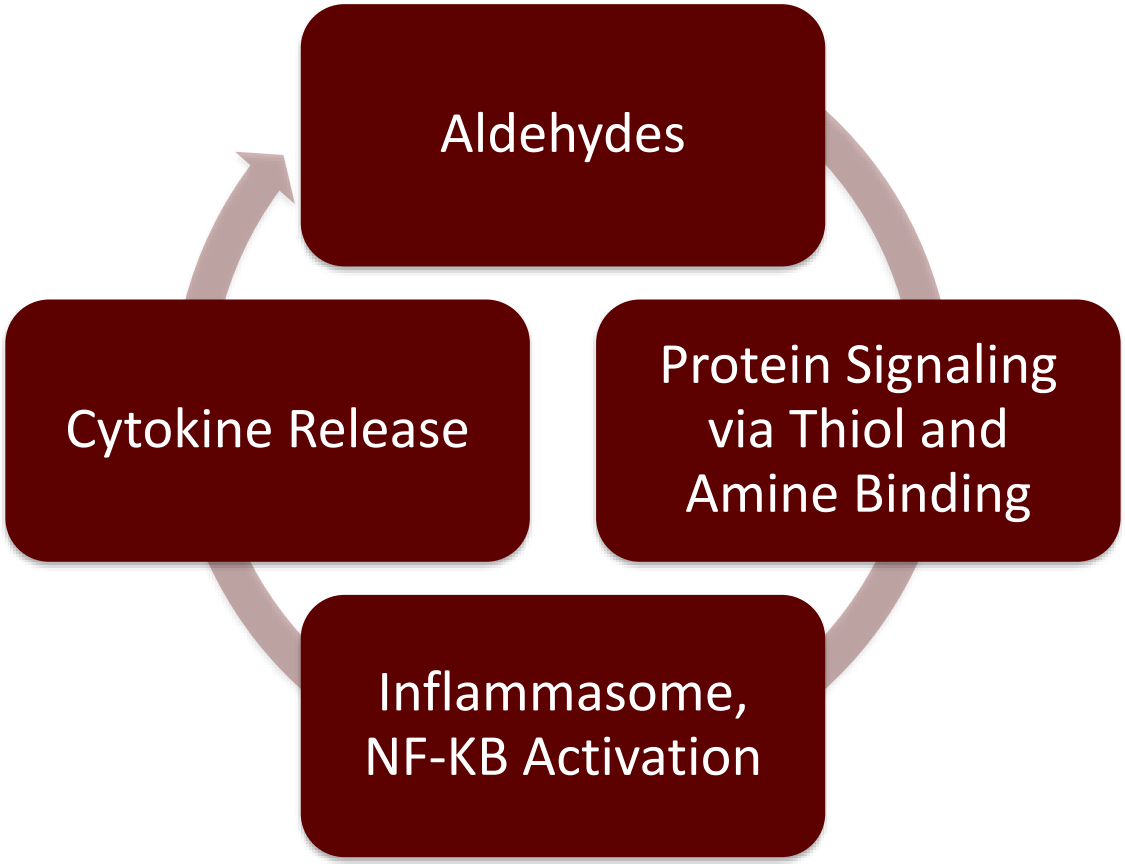
- Talia Technology: Speaker, Advisory Board
- Tear Lab: Advisory Board, Speaker, Shareholder
- Tear Science: Advisory Board, Speaker
- Topcon: Clinical Research Grant
- Topivert: Consultant
- Vistakon: Advisory Board, Clinical Research
- Xoma, Servier: Clinical Investigator, Advisor
- 1-800-DOCTORS: Advisory Board, Shareholder
- Virginia Eye Consultants & Surgery Center: Owner

Aldehydes Are Mediators of Disease

- Directly toxic, modify cellular constituents, and pro-inflammatory
- Metabolized by enzymes called aldehyde dehydrogenases
- High levels are implicated in inflammatory diseases and in inborn errors of metabolism with genetic mutations in aldehyde-related enzymes



Aldehyde Traps: A Novel Therapeutic Approach

Aldehyde Binding

- Aldeyra's compounds rapidly trap free aldehydes

Adduct Transport

- Trapped aldehydes are transported inside the cell

Cellular Degradation

- Drug and aldehydes are metabolized within hours

Aldeyra is not aware of any similar technology, and is developing a series of novel aldehyde traps.

Noninfectious Anterior Uveitis Phase 2 Clinical Design

Dosing	ADX-102 0.5% Topical Ocular Pred Forte® 1% Topical Ocular
Randomized	Active-Controlled 1:1:1 • ADX-102 QID, • Pred Forte® QID Taper, • ADX-102 QID + Pred Forte® BID Taper
Enrollment	45 Patients with Active Disease
Treatment Time	6 Weeks
Endpoints	Cell Count, Flare, Symptoms

ADX-102 Reduced Inflammation in NAU Phase 2

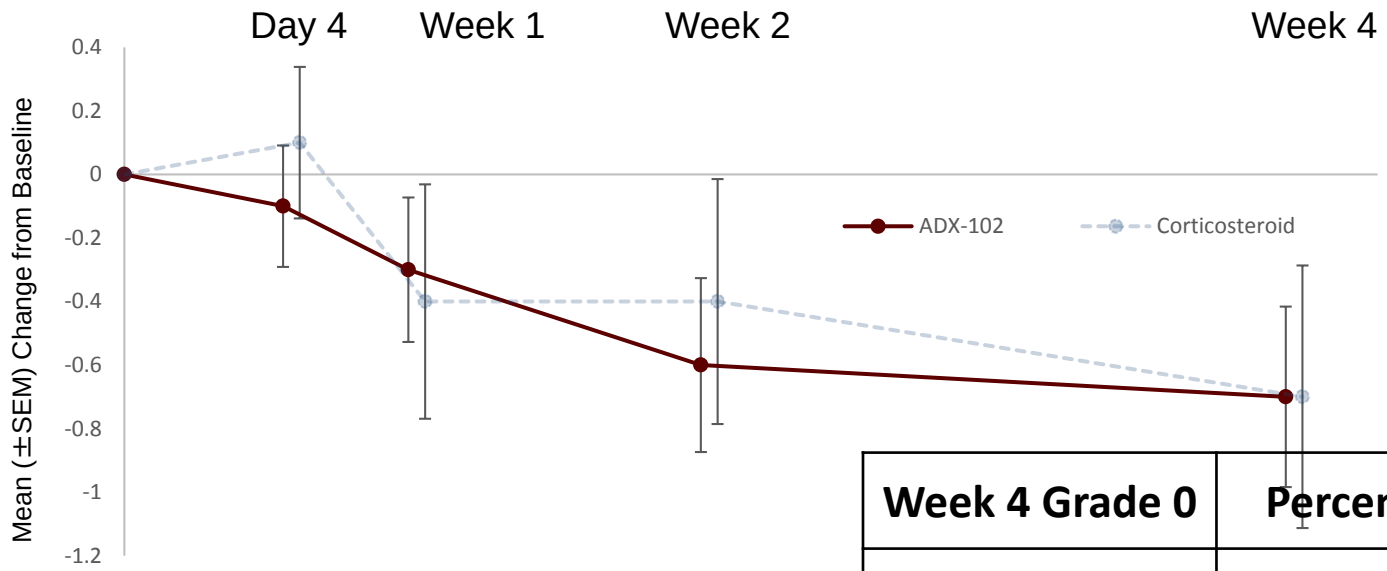
	ADX-102 (n=15)	Pred Forte (n=13)	ADX-102 + Pred Forte (n=16)
Week 2 Cell Grade 0	5 (33%)	4 (31%)	5 (31%)
Week 8 Cell Grade 0	7 (47%)	6 (46%)	7 (44%)
≥ 1 Cell Grade Reduction	8 (53%)	6 (46%)	8 (50%)
Rescue Medication Required	3 (20%)	5 (38%)	4 (25%)

- Grade 0 = cell count of zero or one in anterior chamber
- Patients were rescued at investigator discretion if no improvement or worsening of cell count

ADX-102 Reduced Inflammation in NAU Phase 2

Change from Baseline in Anterior Chamber Cell Grade over Time

(ITT Population, Last Observation Carried Forward)

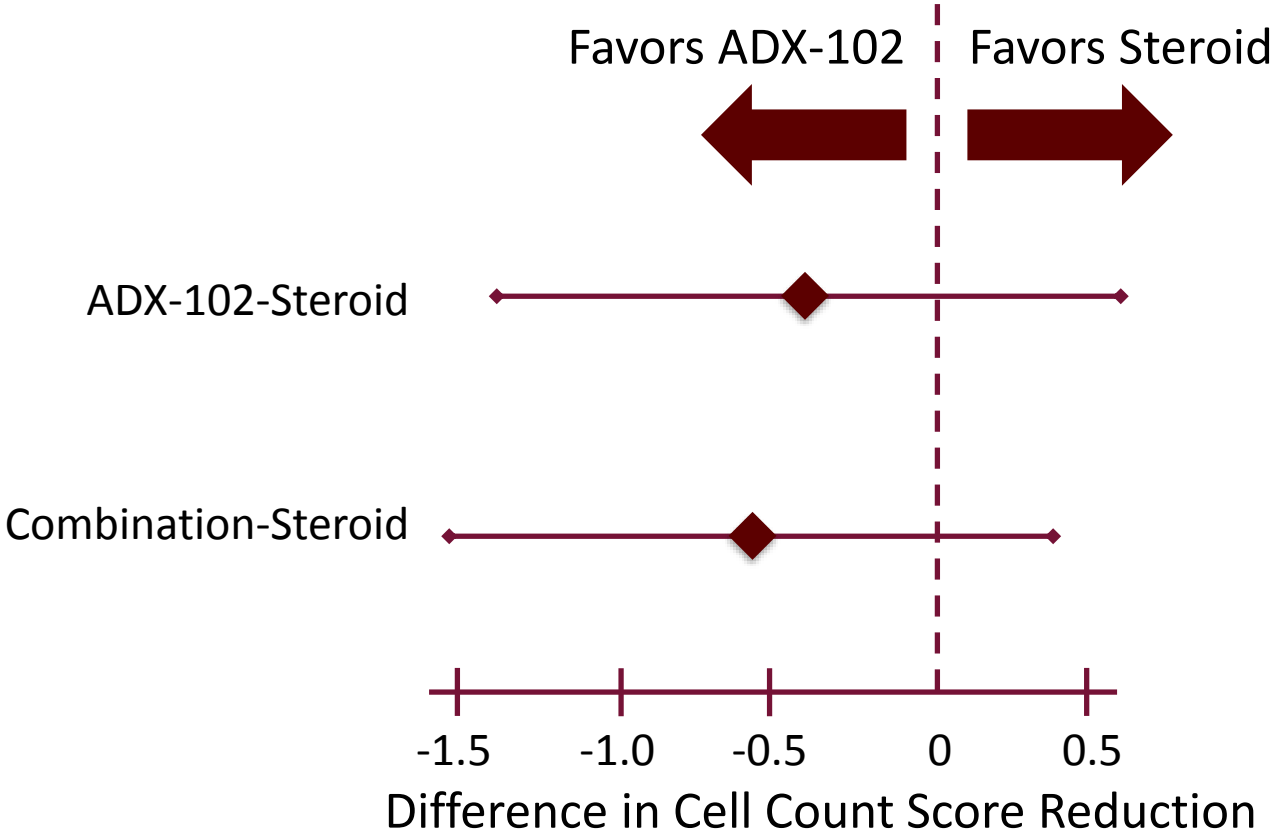


Week 4 Grade 0	Percent of Subjects
ADX-102	**53%** (8/15)
Corticosteroid	**38%** (5/13)

ADX-102 monotherapy effective in the treatment of noninfectious anterior uveitis

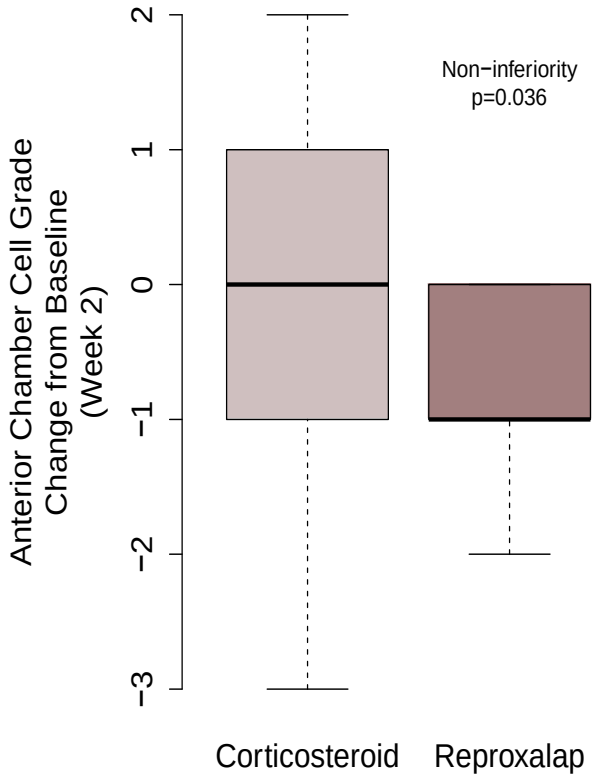
ADX-102 Greater Effects than Corticosteroid in Post Hoc Baseline-Adjusted Analysis

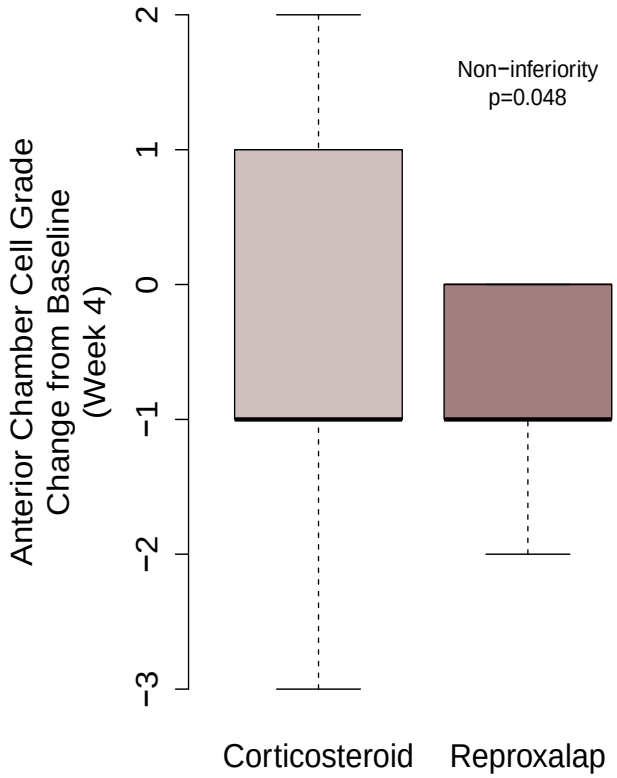
Baseline-Adjusted 95% Confidence Interval of Difference in Means at Week 2
(Last Observation Carried Forward)



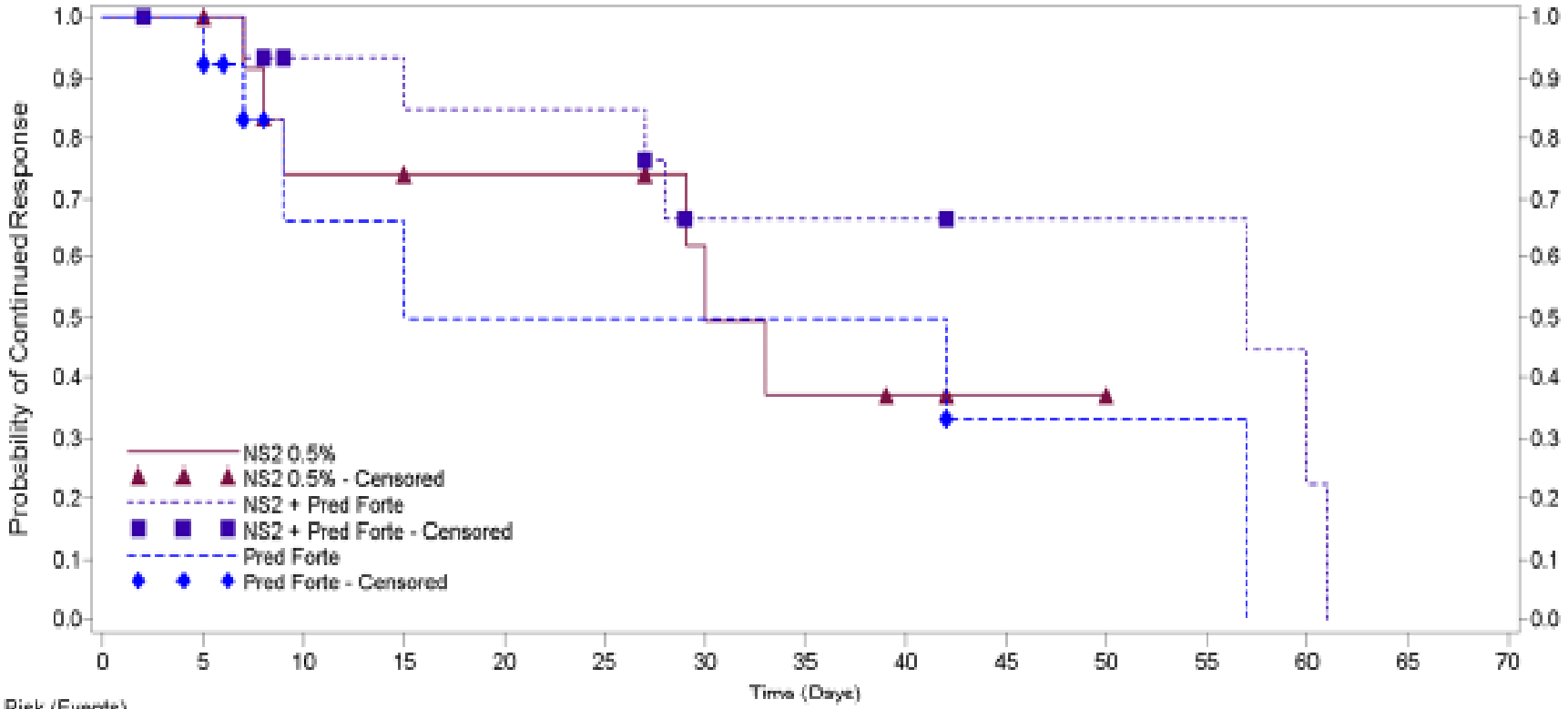
ADX-102 Statistically Non-Inferior to Corticosteroid Monotherapy

Using a Mann-Whitney U test at Week 2 & 4 (Last Observation Carried Forward).





ADX-102 Sustained Grade 0 Responses Time to ACC Treatment Success

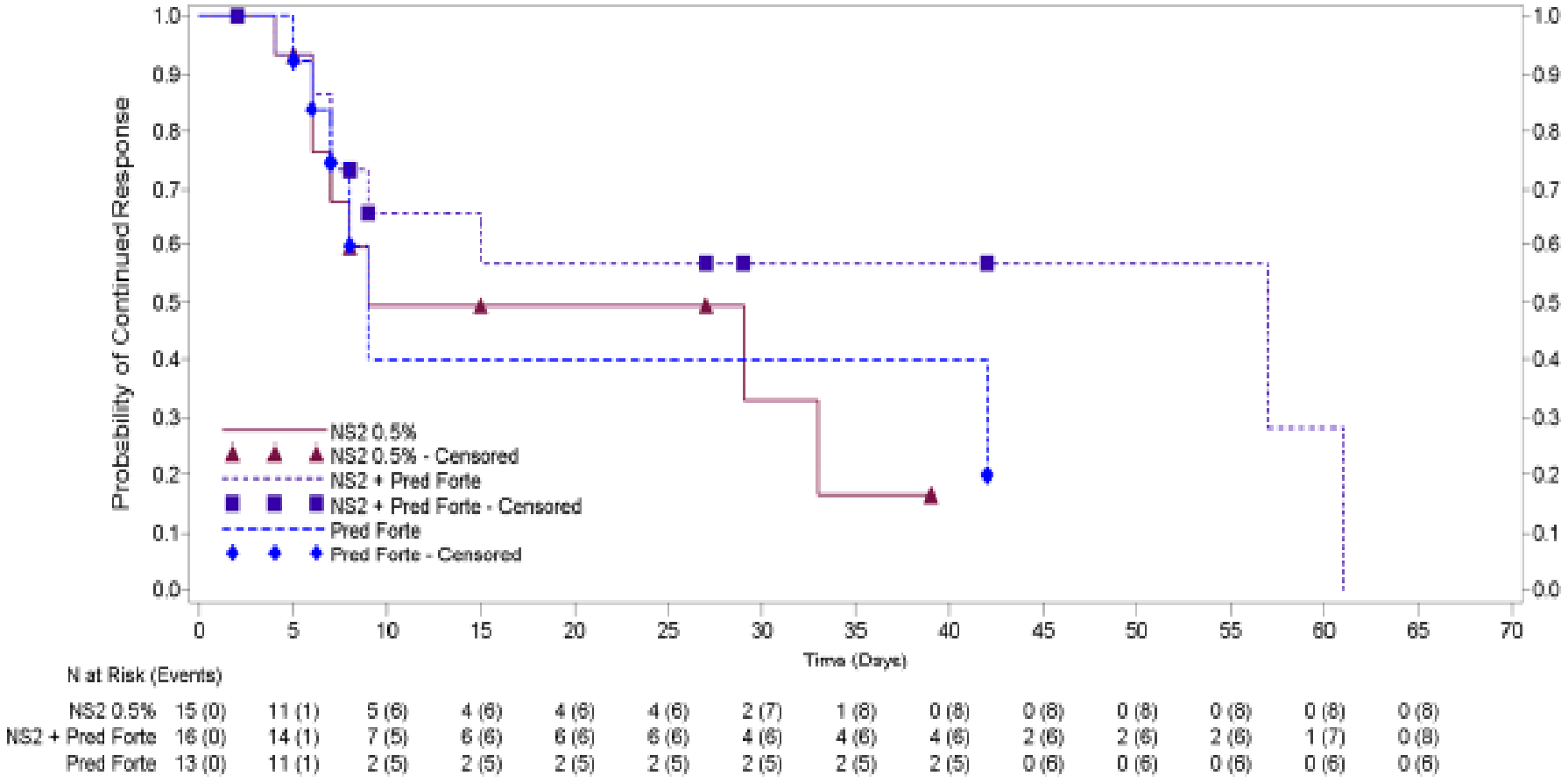


N at Risk (Events)

NS2 0.5%	15 (0)	12 (0)	8 (3)	7 (3)	7 (3)	7 (3)	4 (5)	3 (6)	2 (6)	1 (6)	0 (6)	0 (6)	0 (6)	0 (6)
NS2 + Pred Forte	16 (0)	15 (0)	11 (1)	10 (2)	10 (2)	10 (2)	6 (4)	6 (4)	6 (4)	3 (4)	3 (4)	3 (4)	1 (6)	0 (7)
Pred Forte	13 (0)	11 (1)	4 (3)	3 (4)	3 (4)	3 (4)	3 (4)	3 (4)	3 (4)	1 (5)	1 (5)	1 (5)	0 (6)	0 (6)

Time to treatment success--defined as the number of days from the initiation of study drug to the date that the anterior chamber cell grade reached and sustained a grade of 0--is estimated using the method of Kaplan-Meier. Subjects who do not experience treatment success are censored at the date of discontinuation from treatment, final office visit, or rescue. Differences between treatment groups and the Pred Forte group are assessed using a log-rank test (K-M). Log-rank p value 0.759 ADX-102 vs Pred Forte

ADX-102 Time to ACC Grade Reduction



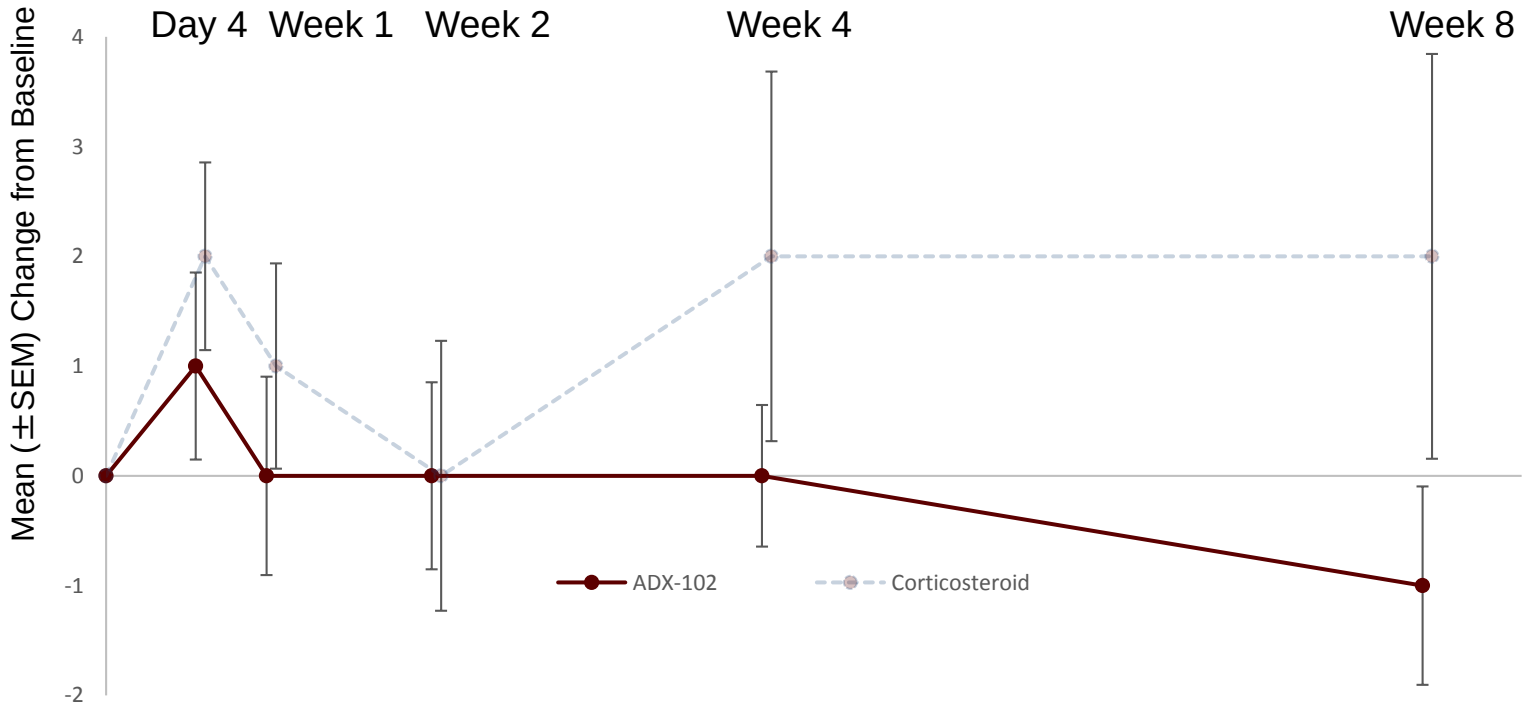
N at Risk (Events)

NS2 0.5%	15 (0)	11 (1)	5 (6)	4 (6)	4 (6)	4 (6)	2 (7)	1 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)	0 (8)
NS2 + Pred Forte	16 (0)	14 (1)	7 (5)	6 (6)	6 (6)	6 (6)	4 (6)	4 (6)	4 (6)	2 (6)	2 (6)	2 (6)	1 (7)	0 (8)
Pred Forte	13 (0)	11 (1)	2 (5)	2 (5)	2 (5)	2 (5)	2 (5)	2 (5)	2 (5)	0 (6)	0 (6)	0 (6)	0 (6)	0 (6)

Time to cell grade reduction--defined as the number of days from the initiation of study drug to the date that the anterior chamber cell grade reached a grade of at least one less than baseline and did not increase thereafter-- is estimated using the method of Kaplan-Meier. Subjects who do not experience cell grade reduction are censored at the date of discontinuation from treatment, final office visit, or rescue. Differences between treatment groups and the Pred Forte group are assessed using a log-rank test (K-M). Log-rank p value 0.650 ADX-102 vs Pred Forte

ADX-102 Did Not Increase Intraocular Pressure in this Noninfectious Anterior Uveitis Phase 2 Clinical Trial

Change from Baseline in Intraocular Pressure (mmHg) over Time (Safety Population)



Increase in intraocular pressure, which may lead to glaucoma, is a major corticosteroid toxicity that is not apparent with ADX-102.

Study Efficacy Summary

- No statistically significant differences for anterior chamber cell count or flare were observed between groups in:
  - Time to sustained grade of 0
  - Proportion of subjects with sustained grade 0
  - Time to sustained reduction of ≥1-point grade
  - Subject proportion with sustained ≥1-point grade reduction

- Post hoc inference testing showed that the Least Square mean change from Baseline in ACC grade for the ADX-102 and combination treatment groups was consistently greater than the Pred Forte group

- These results suggest that ADX-102 treatment alone, or in combination with PA, was effective in the treatment of NAU, with activity that was statistically non-inferior to PA monotherapy*.

*Trial not statistically powered for non-inferiority.

Study Safety Summary

- Overall, safety findings indicate ADX-102 0.5% ophthalmic solution was well tolerated over a 6-week treatment duration

- No safety issues anticipated for future studies of topical ADX-102 in subjects with anterior uveitis:
  - No SAEs during study
  - Most TEAEs were mild or moderate
  - TEAEs most commonly related to ocular irritation

- Aligned with the previous clinical studies, no IOP increases were identified with ADX-102 0.5% in this study

- ADX-102 Generally Well-Tolerated in Noninfectious Anterior Uveitis Patients

Conclusions

- These results suggest that ADX-102 treatment alone, or in combination with 1% Pred Forte®, was effective in the treatment of Noninfectious Anterior Uveitis
- ADX-102 was statistically non-inferior to PA monotherapy in this clinical trial
- ADX-102 Ophthalmic Solution is currently being studied in a Phase 3 study in Noninfectious Anterior Uveitis

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